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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,707	06/07/2001	Theresa M. Allen	5325-0148.34	1073

22918 7590 07/14/2004

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,707	ALLEN ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,25-32 and 57-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,25-32 and 57-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The filing of RCE dated 3-12-04 and the supplemental amendment dated 4-16-04 are acknowledged.

Claims included in the prosecution are 21-22, 25-32 and 57-70.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21-22, 25-32 and 57-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'micellar suspension' now added in claim 21 does not appear to have support in the specification as originally filed

and therefore, deemed to be new matter. Applicant points out to page 9, lines 25-29 and page 29, lines 16-19; the examiner is unable to find the expression, 'micellar suspension' at these locations.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 21-22, 25-32 and 57-70are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,120,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims recite a conjugate of polyethylene glycol (PEG) wherein one end is connected to a targeting ligand having biding affinity for a receptor expressed on a cell surface and the other end to a lipid. The patented claims recite a composition having the claimed polymer conjugate; the conjugate is lipid derivatized PEG attached to ligands for specific binding to target cell surface receptors (see col. 8, lines 58-60 and patented claims 8-9, 13 and 15 in particular). Instant conjugate is therefore, included in the patented claims.

5. Claims 21-22, 25-32 and 57-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,891,468. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims recite a conjugate of polyethylene glycol (PEG) wherein one end is connected to a targeting ligand having biding affinity for a receptor expressed on a cell surface and the other end to a lipid. The patented claims recite a composition having the claimed polymer conjugate; the

conjugate is lipid derivatized PEG attached to ligands for specific binding to target cell surface receptors (see col.11, line 25 through col. 12, line 35 and patented claims 3 and 8-10). Claimed ligands are art known ligands. Instant conjugate is therefore, included in the patented claims.

6. Claims 21-22, 25-32 and 57-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 66-69 of copending Application No. 10/115,566. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims recite a conjugate of polyethylene glycol (PEG) wherein one end is connected to a targeting ligand having biding affinity for a receptor expressed on a cell surface and the other end to a lipid. The claims in the said copending application recite a liposome conjugated to a protein through a linker which is a hydrophilic polymer. The hydrophilic polymer in turn is attached to a component of the liposome. As described in the specification in the copending application, various instant ligands come under the classification of proteins (table 1 in the specification of the copending application). Instant conjugate is therefore, included in the claims of said copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21-22, 25-26, 57, 60-61 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/21281 of record.

WO discloses a conjugate wherein one end of PEG is attached to DSPE and the other end to a polypeptide. The polypeptides disclosed are monoclonal antibodies for tumor specific antigens or biotin (water soluble vitamin). The molecular weight of PEG ranges from 1000 – 10,000 Daltons. (note abstract, page 8, lines 15-25; page 11, line 14 through page 13, line 29; page 15, lines 9-31).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 21-22, 25-32 and 57-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/21281 cited above.

The teachings of WO have been discussed above. What are lacking in WO are the explicit teachings of the attached ligands are for binding to the receptors expressed on the cell surface. However, since the goal of WO is to target the receptors for which the ligands direct the liposomes with subsequent binding to the receptors, it would have been obvious to one of ordinary skill in the art to

attach any ligand including the claimed art well known ligands from the teachings and guidance provided by WO with a reasonable expectation of success.

11. Claims 30, 32, 57-59, 65 and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/21281 cited above, further in view of Kilpatrick (4,913,902).

The teachings of WO have been discussed above. As pointed out above, what is lacking in WO is the use of ligands such as insulin and pyridoxal, ligand for folate receptors. Attachment of these ligands in the compositions of WO would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since Kilpatrick teaches that these ligands are commonly used in directing liposomes to the receptors for these ligands (note col. 3, line 9 et seq.).

12. Claims 28-29, 32, 63-64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/21281 cited above, further in view of Margalit (5,603,872).

The teachings of WO have been discussed above. As pointed out above, what is lacking in WO is the use of ligands such as EGF. Attachment of EGF in the compositions of WO would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since Margalit teaches that EGF is commonly used in directing liposomes to the receptors for EGF (note abstract).

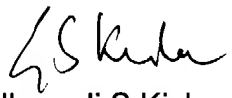
Nagy (5,985,852) is cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is

(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK